CLINICAL RESEARCH CURRICULUM AWARD

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P.T.

National Institutes of Health

Letter of Intent Receipt Date: September 23, 1998
Application Receipt Date: October 21, 1998

PURPOSE

The National Institutes of Health (NIH) invites educational and research institutions to apply for the new Clinical Research Curriculum Award (CRCA) (K30). This program will be supported by all NIH Institutes and Centers.

The CRCA is an award to institutions and addresses, in part, the NIH's initiative to improve the quality of training in clinical research. The NIH recognizes that highly trained clinical researchers are needed in order to capitalize on the many profound developments and discoveries in fundamental science and to translate them to clinical settings. This RFA is intended to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators. The CRCA supports the development or improvement of core courses designed as in-depth instruction in the fundamental skills, methodology, theories, and conceptualizations necessary for the well-trained, independent, clinical researcher. While many NIH programs support research experiences for new clinicians, not all of these trainees have the opportunity to receive formal course work in the design of clinical research projects, hypothesis development, biostatistics, epidemiology, and the legal, ethical and regulatory issues related to clinical research. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research, to support or expand their programs or to improve the quality of instruction. The goal of this program is to improve the training of the participants, so that upon completion of their training, they can more effectively compete for research funding.

For the purpose of this award, clinical research includes: patient-oriented research, epidemiologic and behavioral studies, and outcomes or health services research. The NIH defines patient-oriented research as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes the development of new technologies, mechanisms of human disease, therapeutic interventions and clinical trials.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Clinical Research Curriculum Award, is related to the priority area of human resource development. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/512-1800) or electronically (http://odphp.osophs.dhhs.gov/pubs/hp2000).

ELIGIBILITY REQUIREMENTS

Institution: Applications will be accepted from domestic, non-Federal organizations, such as medical, dental or nursing schools, or from comparable institutions of higher education, or research institutions that have strong, well-established clinical research and/or clinical research training programs. The applicant institution must have a highly trained faculty that is active in clinical research, as evidenced by current research support, and have the commitment and capability to provide the core curriculum to individuals in the development of a clinical research career. Institutions with a substantial clinical research portfolio along with a sufficiently large group of individuals in some aspect of clinical research training and career development are eligible to apply. An institution may submit only one application. Applicants are encouraged to develop consortia in a common geographic location to enhance the depth of their faculty and participant pool, or to improve the quality of the educational experience.

Participants: All participants must be U.S. citizens, non-citizen nationals or lawfully admitted permanent residents of the U.S. This program is intended to include participants who hold the following degrees: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), doctorally prepared nurses, Ph.D. with clinical responsibilities, and other similar categories who could benefit from a core curriculum for clinical research. Since clinical research is

multidisciplinary, participants in this program should represent diverse academic backgrounds. Interactions during the early years of career development may serve to enhance the team approach necessary to meet the multidisciplinary challenges of clinical research. Ph.Ds who want to become involved in clinical research may also participate.

This program is intended to include individuals with NIH support (F32, T32, Ks, M01-CAPS, etc.) as well as non-NIH support for training and career development.

The National Heart, Lung, and Blood Institute will administer this program for the NIH. All potential applicants are strongly advised to contact the NHLBI/NIH staff listed below to discuss their eligibility and the specific provisions of this award.

MECHANISM OF SUPPORT

Awards in response to this RFA will use the K30 mechanism. The program award provides five years of support and is renewable.

FUNDS AVAILABLE

A total budget for FY 1999 of $4 million will be committed to fund applications submitted in response to this RFA. This funding level is dependent upon the receipt of a sufficient number of applications of high merit. The average annual total cost per award is expected to be $200,000. It is anticipated that approximately twenty awards will be made in FY 1999. The NIH plans to reissue this RFA again next year.

TRAINING OBJECTIVES

Background: The NIH is launching a new initiative to attract talented individuals to the challenges of clinical research and to provide them with the critical skills that are needed. There is a core of knowledge and skills common to all areas of clinical research that should form the foundation of clinical research training. These skills will also serve to improve the ability of new clinical investigators to develop hypothesis and draft sound research proposals for support. This initiative is consistent with the recommendations of the NIH Director's Panel on Clinical Research (http://www.nih.gov/news/crp/index.html), as well as those from the Institute of Medicine Committee on Addressing Career Paths for Clinical Research.

Goals and Scope: The objective of this RFA is to improve the quality of clinical research training by providing didactic courses in the fundamental skills needed for clinical research. The long-term goal is to produce clinical researchers who are competitive in seeking research support and knowledgeable about the complex issues associated with conducting sound clinical research. This CRCA is open to educational and research institutions that do not currently provide such a didactic program, as well as to those that have well-established clinical research training programs. This award provides resources to allow institutions to conduct a comprehensive clinical research curriculum. A curriculum for each group of participants should be designed for two years, and the applicant institutions should justify the period and describe plans for enrolling a cohort of participants each year. The planning, direction, and execution of the instructional program will be the responsibility of the program director and the awardee institution, but must be consistent with the goals of the CRCA. The curriculum must span a variety of fields of research and encompass a broad range of clinical scientists, who are interested in the mechanisms of human disease, the genetics of complex disorders, and therapeutic responsiveness. The core curriculum is to include an array of clinical research-related topics of general interest such as biostatistics, bioethics, clinical trials design, observational study design, Federal policies and regulations that address research with human subjects (e.g., 45CFR46, FDA INDs, inclusion of women and minorities as well as children in clinical research projects), scientific writing for publication and competitive grants. Other topics may include patenting and material transfer agreements as well as legal and social issues. The scope of the core curriculum can be flexible to meet the perceived needs of the institution.

The program may also include advanced, specialized courses for epidemiology, outcomes research, pharmacokinetics, computer-based training for complex data management and analysis, effective use of the Internet for sharing or accessing data, technologies, data visualization, etc. In addition, institutions may propose providing support for appropriate candidates to earn a master's degree in a relevant area - e.g., public health. The proposed program should also have the flexibility to accommodate participants with different levels of experience.

Individuals participating in the program should demonstrate a high level of interest and the potential for the pursuit of innovative clinical research as a major focus in their career plan, and plan to enter into a long-term clinical research career. Institutions or consortia applying for an award must be able to demonstrate a historical record of attracting and producing such individuals. If not already ongoing, new programs should have the faculty and plans for recruiting participants to enter the didactic program.

Environment: The institution must have high-quality clinical research and qualified faculty in clinical research. The proposed faculty should be actively engaged in the design and conduct of such research, and also have demonstrated a successful record in obtaining peer reviewed federal and non-federal funding for such activities. The institution must develop an innovative, multidisciplinary program to maximize the available research and educational resources. Applicant institutions must describe the pool of participants and must demonstrate experience in preparing individuals for careers in clinical research.

Program: The program award provides five years of renewable support. The award is intended to support the conduct of a high-quality didactic program in the fundamentals needed for independent clinical research. Applicants must provide a detailed description of the program including courses offered, frequency of classes, selection criteria for participants entering the program, and target goal of enrollment into the program. The program must be operational within one year of the award.

Program Director: The Program Director (PD) should possess the clinical research expertise, leadership and administrative capabilities required to coordinate and supervise an interdisciplinary didactic program of this scope. The Director should also be experienced in the design and management of programs for the development of clinical investigators, and should be able to demonstrate a superior record of preparing individuals for independent clinical research. The Program Director should be the role model for the participants. He or she should be personally engaged in clinical research as well as in the mentoring of new investigators. A minimum of 25% of the PD's effort is required.

Faculty: Faculty involved in the CRCA should have a record of providing the type of curriculum required under this award. For example, faculty trained in biostatistics, data analyses and data management are recommended. Generally, faculty will also be accomplished investigators. The percent of faculty effort planned for the courses should be described.

SPECIAL REQUIREMENTS

Advisory Committee: The Program Director must establish an Advisory Committee for this program to provide ongoing assessment and monitoring. Clinical and basic science departments participating in this program should be represented on the committee. The committee's responsibilities might include: selecting participants, evaluating each participant's progress, and monitoring the overall effectiveness of the didactic program and updating it as needed. A detailed

description should be provided of the committee's composition, function, and organizational structure.

Assessment: Plans for an assessment of the program by the Advisory Committee should be described. The Annual Progress Report of the grant should provide a summary of the program participants' progress. Institutions should be capable of providing information about the career progression of all participants who receive training supported by the CRCA.

Allowable Costs: Allowable costs may include personnel (support for the Program Director, faculty, and administrative support), supplies, travel, honoraria and per diem for outside speakers, seminars, development of course materials, consultants, and other costs, such as printing, telephone, audio-visual, postage, recruitment materials, and computer software. In addition, travel and related costs and tuition for program participants to attend courses (including courses at another site) are appropriate when necessary. The facilities and administrative (F&A) cost rate for K30 awards is 8 per cent of modified total direct costs, or at the actual F&A cost rate, whichever is less.

The compensation for the PD must not exceed the actual institutional salary rates for the effort being devoted to the CRCA. In addition, salary rates must not exceed an annual salary level of $125,000 plus fringe benefits (a maximum of $62,500 for 50% effort). The PD must devote at least 25% effort and no greater than 50% effort to this award and may also be a principal investigator on other research awards. The PD may devote up to a total of 100% combined effort on the CRCA and as an investigator on any other Federal or non-Federal awards and may receive remuneration from such sources accordingly.

Funds may not be requested to directly support the individual trainees. Their activities are expected to be supported by other Federal or non-Federal sources.

The NIH anticipates organizing annual meetings of Program Directors and other staff members to exchange information about effective approaches in the training of new clinical investigators, including the sharing of course materials that may be widely useful. The first annual meeting will occur approximately one year after the initial date of award. Requests for funds to support the travel of the PD and another faculty participant to the Washington, D.C. area to attend this meeting should be included in the application.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 23, 1998, a letter of intent that includes a descriptive title of the proposed program, the name, address, telephone, FAX, and E-mail numbers of the Program Director, the names of other key personnel, the participating institutions and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains permits the NIH to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to:

Lawrence Friedman, M.D.
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 8100
Bethesda, MD 20892
Telephone: (301) 435-0422
FAX: (301) 480-1864
Email: friedmal@gwgate.nhlbi.nih.gov

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact the staff person listed under INQUIRIES early in the planning phase of the CRCA application. Such contact will help ensure that applications are responsive to the overall intent of this award.

To identify the application as a response to this RFA, check "YES" on item 2a of page 1 of the application and enter OD-98-007, CRCA.

Applications are to be submitted on grant application form PHS 398 (rev. 5/95-use instructions in Section IV as appropriate) and will be accepted on or before October 21, 1998. Forms are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive MSC 7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, FAX: (301) 480-0525, Email: asknih@od.nih.gov.

The completed, signed original and five legible, single-sided copies of the application and five copies of the appendices must be sent or delivered to:

CENTER FOR SCIENTIFIC REVIEW (formerly Division of Research Grants)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817-7710 (for express/courier service)

The application must address the following issues:

1. Didactic Courses: Describe the content of the proposed courses and their potential benefits to the participants.
2. Institutional Commitment: Provide information establishing the commitment of the applicant institution, the program director, and the faculty to providing didactic experiences necessary for an independent career in clinical research.
3. Career Development Plans: Describe how the didactic experiences supported by this award will advance the career development plans for prospective participants.
4. Available Participants: Describe the pool of potential participants including information about the types of prior clinical and research training. Also describe how appointments are made to the broader training program in clinical research, e.g., the Mentored Clinical Scientist Development Program Award (K12). Describe the composition of the selection committee and the criteria to be used for selection. Provide demographic data and the number of individuals participating in current training programs, e.g., T32, K12, K08, F32, etc. and others eligible for this program. This information will be evaluated to determine whether a sufficient number of participants will be available for the proposed CRCA.
5. Research Environment: Describe to the extent possible the types of research experiences that will be available to the participants upon completion of the didactic training supported by the CRCA.
6. Instruction in the Responsible Conduct of Research: Applicants must include plans for instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction; and the amount and nature of faculty participation. No award will be made if an application lacks this component.
7. Career Outcomes of Former Participants: At the time of renewal, applicants submitting renewal applications must include an account of the career outcomes of the participants who receive training supported by the CRCA. Include positions held, research involvement,

publications, major accomplishments, current status of participants supported by this program and other evidence that award is meeting the objectives described above.
8. Program Effectiveness: The applicant institution is to include a component to assess the effectiveness of the proposed curriculum, including benchmarks against which success of the program can be measured. This component will be an essential review criterion against which renewal applications will be evaluated.

BUDGET

The review group will critically examine the proposed budget and recommend an appropriate budget for each recommended application within the guidelines stated above.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR (formerly DRG) and for responsiveness by the NHLBI. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NHLBI in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Heart, Lung, and Blood Advisory Council.

Review Criteria

The review criteria for the Clinical Research Curriculum Award will include:

- Quality of the content of courses and adequacy of the syllabus.

- Clinical, scientific and administrative leadership qualifications and experience of the program director.

- Qualifications of the faculty: portfolio of on-going funded projects, publications and training experience in the context of achieving the objectives of this RFA.

- Criteria for selecting participants, publicizing the availability of the program to potential participants, and demonstration of a sufficient number of high quality participants.

- Adequacy and availability of any necessary institutional facilities and resources.

- Adequacy of the membership and functions of the program Advisory Committee.

- Effective plans for program oversight and on-going assessment.

- Appropriateness of the requested budget for the proposed didactic program.

AWARD CRITERIA

Applications will compete for available funds with those submitted and reviewed in response to this RFA. This is a trans-NIH program that is being administered and managed by the National Heart, Lung, and Blood Institute. An NIH Coordinating Committee will, therefore, be established to participate in all phases of this program. Funding decisions will be based on the recommendations of the initial review group, the National Heart, Lung, and Blood Advisory Council(at its May 1999 meeting), and the NIH Coordinating Committee regarding scientific and programmatic merit as well as the availability of funds. The anticipated award date is July 1, 1999. The NIH policy on submission of revised (amended) applications limits the number of such applications to two.

INQUIRES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Lawrence Friedman, M.D.
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 8100
Bethesda, MD 20892
Telephone: (301) 435-0422
FAX: (301) 480-1864
Email: friedmal@gwgate.nhlbi.nih.gov

Ronald G. Geller, Ph.D.

Division of Extramural Affairs
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 7100
Bethesda, MD 20892
Telephone: (301) 435-0260
FAX: (301) 480-3460
Email: rg33k@nih.gov

Belinda Seto, Ph.D.
Office of Extramural Research
National Institutes of Health
Building 1, Room 252
Bethesda, MD 20892
Telephone: (301) 402-9128
FAX: (301) 402-2642
Email: bs11e@nih.gov

Direct inquires regarding fiscal matters to:

Ms. Marie Willett
Grants Operations Branch
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 7128
Bethesda, MD 20892
Telephone: (301) 435-0144
FAX: (301) 480-3310
Email: willettm@gwgate.nhlbi.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93. 855 and 93.856. Awards are made under the authority of title III, Section 301 of the PHS Act as amended. The Code of Federal Regulations, Title 42 Part 52 and Title 45 Part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 to Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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